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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,567	02/25/2005	Iwao Okamoto	OKAMOTO11	3039

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EXAMINER	
ROOKE, AGNES BEATA	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/525,567	OKAMOTO ET AL.	
	Examiner	Art Unit	
	Agnes B. Rooke	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 10/06/2005.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-13 are pending.

This application is a 371 of PCT/JP03/10795 filed on 08/26/2003.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A protein claimed must be purified or isolated, therefore the proper correction is required.

Claims 6 and 7 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 6 and 7 provide for the use of a composition comprising a protein for inhibiting allergy, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 2, 5-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 2, 6, and 7, the phrase "*where one or more amino acid residues are replaced, inserted or added in such a manner that the anti-allergic activity of the protein is not substantially eliminated"* is indefinite, because it is not certain how the structure of the protein looks like after so many mutations that involve replacement, insertion or additions of different amino acids. Also, no reference sequence numbers are provided to these mutated fragments and there is no difference in the words used in the claims, such as "insertion" and "addition." Therefore, the claims are indefinite.

In claims 1, 2, 6, and 7, the word "substantially" is indefinite because in the context of the claim the phrase "the activity is not substantially eliminated" does not specifically define the activity claimed, and thus the claims are indefinite.

Further in claim 5, the sentence starting "*...than the case of without the protein of the agent in the inhibition test of cytokine production using a sample with 2 mg/ml protein concentration, disclosed in the specification*" is indefinite, since the wording of eth claim and a referral to the specification in claim 5 is indefinite, since it is uncertain to what specific part of eth specification the Applicants refer in the instant claim.

Claims 8-13 are included in this rejection because they depend from rejected independent base claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, at the time the invention was made, of the specific subject matter claimed. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

MPEP § 2163 further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163 does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art*, (2) *partial structure*, (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention*. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

In the instant case, the claims are drawn to an anti-allergic agent which comprises a protein which comprises SEQ ID NO:1 or SEQ ID NO:2 or SEQ ID NO:3 or SEQ ID NO:4 where one or more amino acid residues are replaced, inserted or added in such a manner that the anti-allergic activity of the protein is not substantially

eliminated. Further, a composition of royal jelly or purified royal jelly is claimed where the composition is not in itself disclosed.

(1) Level of skill and knowledge in the art: is high;

(2) Partial structure: of SEQ ID NOs:1-4 is not disclosed or specifically discussed in the specification; the Applicant claims undefined number of different mutated versions of SEQ ID NOs; 1-4, but none of them are disclosed or discussed in the specification;

(3) Physical and/or chemical properties: not claimed;

(4) Functional characteristics: Claims refer to a anti-allergic agent that is composed of SEQ ID NOs: 1-4 or different mutated versions of these proteins;

(5) Method of making the claimed invention: not claimed.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad genus. Claims 1-13 are broadly generic to all possible fragments of SEQ ID NOs: 1-4 encompassed by the claims. The possible variations are enormous to any class of fragments of SEQ ID NOs: 1-4. Since the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of different fragments with these different mutations or variations claimed in SEQ ID NOs: 1-4.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention.

See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

In claims 1-13, the function of the different mutated fragments of SEQ ID NOs: 1-4 is not disclosed, since an amino acid sequence where one or more amino acid residues are replaced, inserted or added, does not necessary have the same activity as the full SEQ ID NOs: 1-4. Therefore, the structure of the mutated polypeptides or their fragments does not correspond with their function and the written description requirement is not satisfied.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Katoka et al., Analysis of Anti-allergic Function of Royal Jelly, Natural Medicines, (2001), 55(4), p. 174-180, see **Abstract.**

Katoka et al. teach examination whether royal jelly exhibits anti-allergic functions similar to those of *Perilla frutescens* leaf extract (PFE) using an immediate hypersensitivity; where in a manner similar to that observed with PFE, intraperitoneal

administration of RJ significantly inhibited both using an immediate hypersensitivity model, in which BALB/c mice were immunized with ovalbumin; in a manner similar to that observed with PFE, intraperitoneal administration of RJ significantly inhibited both OVA-specific IgG1 and IgE production, and IL-4, IL-5, and IL-10 production by spleen cells stimulated with OVA; where in contrast to PFE, administration of RJ also inhibited IFN-γ production by OVA-stimulated spleen cells, and tended to down-regulate OVA-specific IgG2a production; where also oral administration of RJ also resulted in significant inhibition of both OVA-specific IgE and total IgE production; where these results suggest that RJ exhibits anti-allergic functions through a different mechanism from that of PFE. See Abstract.

Claims 1-11 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Oka et al., Suppression of allergic reactions by royal jelly in association with the restoration of macrophage function and the improvement of Th1/Th2 cell responses, International Immunopharmacology, 1, 2001, p. 5212-532.

Oka et al. teach in the Abstract that oral administration of royal jelly (RJ) to immunized mice significantly decreased the serum levels of antigen-specific Ig E and hypersensitivity reactions of ear skin; where the results suggested that RJ suppressed antigen-specific Ig E production and histamine release from mast cells in association with the restoration of macrophage function. See also Figure 1 and Figure 2, page 524, where RJ was administered orally. (Claims 3, 4, 5)

Claims 1 and 2 are included in this rejection because they refer to an anti-allergic agent comprising SE QID NO:1 and SEQ ID NO:3 or SEQ ID NO:2 or SEQ ID NO:4, respectively, where one or more amino acid residues are replaced, inserted or added in such a manner that the anti-allergic activity of the protein is not substantially eliminated. Thus, the mutations claimed in SEQ ID NOs: 1-4 could encompass any royal jelly protein, as one disclosed in Oka et al., for example.

Claim 6 is included in this rejection because the claim refers to a method for inhibiting allergy, where a protein is used that has an amino acid sequence of SEQ ID NO:3 or where one or more amino acid residues are replaced, inserted or added in a manner that the activity is not substantially eliminated.

Claim 7 is included in this rejection because the claim refers to a method for inhibiting allergy, where a protein is used that has an amino acid sequence of SEQ ID NO:4 or where one or more amino acid residues are replaced, inserted or added in a manner that the activity is not substantially eliminated.

Both claims 6 and 7 refer to a royal jelly proteins, which structure is completely unknown since undefined replacement, insertion, or addition of amino acids can take place which could read on any royal jelly protein including the royal jelly protein as discussed in Oka et al.

Claims 11 and 13 are included in this rejection because the royal jelly in Oka et al. is administered orally, therefore it is a pharmaceutical (claim 13) and it can be administered orally in a form of a food or beverage (claim 11).

Claims 1-5 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamada et al. (6,165,982).

Yamada et al. teach cosmetic composition where royal jelly, and anti-allergic agents are used in a cosmetic. See Abstract; column 5, line 35, and line 39.

Prior art of record:

According to the USPTO search engine GenCore version 5.1.7:

1. **SEQ ID NO:1** has 100% in Figure 1, on page 65 , for example, See J. Agricultural Res., (1996), 35, p. 63-68; J. Agricultural Res., (1994), 33, p. 105-111; Cell. Mol. Life Sci. (1998), 54, p. 1020-1030.

2. **SEQ ID NO:2** has 100% identity to the structure disclosed in Eur. J. Biochem. (1997), 249, p. 797-802.; Cell. Mol. Life Sci. (1998), 54, p. 1020-1030; Gene (2003), 303, p. 165-175.

3. **SEQ ID NO:3** has 99.2% identity to the sequence disclosed in J. Agricultural Res. (1994), 33, p. 105-111; J. Agricultural Res. (1996), 35, p. 63-68; Cell. Mol. Life Sci. (1998), 54, p. 1020-1030.

4. **SEQ ID NO:4**, has 99.9% identity to the structure disclosed in JP2001172190 A; Eur. J. Biochem. (1997), 249, p. 797-802; Cell. Mol. Life Sci. (1998), 54, p. 1020-1030; Gene (2003), 303, p. 165-175.

5. Shibuya et al. (U.S. 6,224,872); Yoneda et al. (5,997,852); Matsukawa (U.S. 6,214,352); JP 2002112715 A; Hua (U.S. 5,108,749) teach cosmetic composition that is anti-allergic and where royal jelly is used.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

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Karen Cochrane Carlson PhD

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PRIMARY EXAMINER